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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/505,788 02/17/00 OLSON

R PH-7076-A

EXAMINER

HM22/1010

SCOTT K LARSEN

COLEMAN, B

DUPONT PHARMACEUTICALS COMPANY
C/O E I DU PONT DE NEMOURS AND CO LEGAL

ART UNIT

PAPER NUMBER

1007 MARKET STREET
WILMINGTON DE 19898

1624

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/505,788

Applicant(s)
OLSON

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 25, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) 7, 9, 17, 19, and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-16, 18, 20, and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 1-24 are pending in the application.

This action is in response to applicants' amendment dated July 25, 2001. Claims 1, 2, 4-6, 8, 10, 12, 15-16, 18 and 20 were amended.

Response to Arguments

Applicant's arguments filed July 25, 2001 have been fully considered with the following effect:

1. With regards to Applicant's traversal to the restriction requirement of the last office action, the applicant's amendments and arguments have been fully considered but are not found persuasive. The traversal is on the ground(s) that there are two criteria for a proper requirement between patentably distinct inventions: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the examiner if restriction is not required.

(1) Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where ring B forms an benzoxazepinone, benzothiazepinone, azepinone ring, etc. be patentably distinct from a whole compound where B forms a benzodiazepinone? If a reference for one would not be a reference for the other, then restriction

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is considered proper. Community of properties is not enough to keep benzoxazepinone, benzothiazepinone, azepinone in the same Markush claim with benzodiazepinone, where the Markush expression is applied only to a portion of a chemical compound. It is the compound as a whole benzoxazepinone vs benzothiazepinone vs azepinone vs benzodiazepinone, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

(2) The degree of burden on the examiner is high. The class/subclass search on the **elected invention** was class 540/504, 505, 506, 509, 517 and 518 and class 514/221 which involved 645 US patents. This number does not include the search required in the area of journal articles and foreign patents.

The requirement is still deemed proper and is therefore made FINAL.

2. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of the last office action, which is hereby **withdrawn**.

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3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a)-e) and g)-z) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled f) and aa) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- f) The applicants' stated that "claims 6, 8, 10, 15, 16, 18 and 20 depend from claim 5" which was amended to be a dependent claim of claim 3. However, claims 15, 16, 18 and 20 are not dependent on claim 5, but claim 14 which only allows for 0-2 R¹³ variables attached to the benzo fused radical.
- aa) The applicants' stated that they "provide in the specification utility, a general guideline for measuring and assessing utility, and examples sufficient to enable a person of ordinary skill in the art to determine whether compounds of the present invention effect gamma secretase activity and/or beta-amyloid production". It is not known which diseases and/or disorders other than Alzheimer's disease are associated with gamma secretase activity and/or beta-amyloid production.

Claims 15, 16, 18, 20, 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

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4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of the last office action, which is hereby **withdrawn**.

5. With regards to the provisional 35 U.S.C. § 101 rejection as claiming the same invention as that of copending application 09/469,939 of the last office action, the applicants requested "that this rejection be held in abeyance at this time".

Claims 5, 6, 8, 10-16, 18 and 20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5, 6, 8, 10-16, 18 and 20 of copending Application No. 09/469,939. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. For reasons of record.

6. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending application 09/469,939 of the last office action, the applicants requested "that this rejection be held in abeyance at this time".

Claims 1-4 and 22-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 09/469,939. For reasons of record.

In view of the amendment dated July 25, 2001, the following new grounds of rejection apply:

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Election/Restriction

7. Claims 7, 9, 17, 19 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

8. Claims 1-5, 10, 12-15, 20 and 22-24 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the response to the traversal of the restriction requirement above.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5, 6, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 5 recites the limitation "R¹¹ substituted to the seven membered ring" in the third structural formula in the second row. There is insufficient antecedent basis for this limitation in the claim.

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- b) Claim 6 recites the limitation "R¹¹ substituted to the seven membered ring" in the structural formula in the claim. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 15 recites the limitation "R¹¹ substituted to the seven membered ring" in the third structural formula in the second row. There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 16 recites the limitation "R¹¹ substituted to the seven membered ring" in the structural formula in the claim. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman

Primary Examiner AU 1624

October 5, 2001